NIH POLICY MANUAL

54104 NIH Research Grants Involving Foreign Institutions and International Organizations
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1. **Explanation of Material Transmitted:** This chapter was previously updated 09/01/01 to include information regarding the allowability of limited (8%) Facilities and Administrative costs for foreign institutions and international organizations (see Sections K and Terms and Conditions Applicable to Foreign Grants). This current update is to clarify that the 8% is strictly for Administrative costs and only equipment costs are excluded in computing the 8% allowance.

2. **Filing Instructions:**

   Remove: NIH Manual 54104 dated 09/01/01 in its entirety.
   Insert: NIH Manual Chapter 54104 dated 01/22/02

PLEASE NOTE: For information on:

?? Content of this chapter, contact the issuing office listed above.

?? On-line information, enter this URL: http://www1.od.nih.gov/oma/manualchapters/

?? NIH Manual System, contact Office of Management Assessment, OA, on 496-2832.

NIH RESEARCH GRANTS INVOLVING FOREIGN INSTITUTIONS AND INTERNATIONAL ORGANIZATIONS

A. Purpose:

This chapter states the NIH policies and procedures governing awards of biomedical or behavioral research grants to foreign institutions, international organizations, and to U.S. grantees for projects which have a substantial foreign component.

B. Revisions:

1. This chapter is being revised to update information regarding the allowability of limited (8%) Facilities and Administrative costs for foreign institutions and international organizations (see section K and Terms and Conditions Applicable to Foreign Grants).

2. There is also clarification that the addition of a foreign component requires prior approval for all recipients, regardless of the terms of award (see section G.)

3. In addition, Section N "Management Controls" has been updated to reflect implementation of the Grants Management Compliance Board.

C. Applicability:

The policy is applicable only to NIH grants and cooperative agreements for research projects. It is not applicable to Special Foreign Currency Agreements (P.L.-480 Programs).

D. Background:

The PHS Act Title III, Part A. Sec. 307 (a) states:

"For the purpose of advancing the status of the health sciences in the United States (and thereby the health of the American people), the Secretary may participate with other countries in cooperative endeavors in biomedical research, health care technology, and the health services research and statistical activities authorized by section 306 and Title IX."

Authority for carrying out these objectives has been delegated from the Secretary, DHHS, to the Assistant Secretary for Health and redelegated to the Director, NIH. The Director, NIH, has redelegated this authority as specified in NIH Manual Chapter 1130, Delegations of Authority, Program: Grants and Awards No. 1. In pursuing this objective the NIH recognizes the special opportunities for furthering research programs through the use of unusual talents, resources,

populations, and environmental conditions in other countries which are not readily available in the United States or which augment existing United States resources. At the same time, NIH recognizes that it can support research in other countries only when such research has important specific relevance to the objectives of the NIH authorized in the legislative and appropriation acts of the Congress. Any exercise of this authority will be carried out in harmony with U.S. foreign policy.

E. References:

1. PHS Grants Administration Manual Part 709, Research Grants to Foreign Institutions, International Organizations and to Certain U.S. Grantees for Support of Foreign Activities;

2. NIH Manual Chapter 54510, Referral and Initial Review of NIH Grant and Cooperative Agreement Applications;

3. NIH Manual Chapter 54513, Management and Procedures of National Advisory Councils and Boards in their Review of Extramural Activities

4. NIH Manual Chapter 55201, Change of Grantee Institution;

5. NIH Manual Chapter 1130, Delegations of Authority, Program: Grants and Awards No. 1, Grants-in-Aid;

6. NIH Manual 1895 - Coordination of International Activities.

7. Departmental Deviation providing for limited Facilities & Administrative costs to foreign and international grantees dated March 13, 2001 available by contacting OPERA, 435-0949.

F. Definitions:

1. Foreign Grant: A biomedical or behavioral research grant or cooperative agreement awarded to a foreign institution or international organization.

2. A substantial foreign component of a grant to a U.S. institution is defined as:

a. The use of grant funds to provide support to any significant scientific element or segment of the project which is to be performed outside the U.S. either by the grantee project staff or by a researcher employed by a foreign institution.

b. The use of grant funds in such a manner that it may impact on U.S. foreign policy through the involvement of grantee project staff in the affairs or environment of the

foreign country.

c. Any activity as described above or including the involvement of human or animal subjects whether or not grant funds are expended.

3. Foreign Institution: A private or public nonprofit institution or for-profit organization located in a country other than the United States and its territories and subject to the laws of that country, irrespective of the citizenship of the proposed principal investigator.

Exception: American University of Beirut is considered a domestic institution for purposes of Facilities & Administrative costs and cost sharing and is exempt from the requirements of a review by the Department of State. It is considered foreign for all other purposes.

4. International Organization: An organization which identifies itself as international or intergovernmental with membership from and representing the interests of more than one country, without regard to whether the headquarters and the location of the proposed activity are inside or outside the United States.

If there is any doubt as to whether the grant involves a substantial foreign component, consult the Fogarty International Center (FIC) for an opinion.

G. Policy:

1. Criteria. The proposed foreign grant project must meet all of the following criteria in order to be awarded:

a. The project presents special opportunities for furthering research programs through the use of unusual talents, resources, populations, or environmental conditions in other countries which are not readily available in the United States or which provide augmentation of existing United States resources.

b. The project has specific relevance to the mission and objectives of the awarding Institute or Center **(**IC**)** and has the potential for significantly advancing the health sciences in the United States.

c. The application must be approved by the awarding IC Council/Board.

d. Grants may be awarded only after assurance that the foreign institution is in compliance with human subject, animal welfare, gender and minority requirements.

2. Project Period. The initial project period and each competitive segment thereafter may be awarded for up to five years.

3. Exceptions. Foreign institutions may not be awarded grants for program projects, centers, resources**,** or Institutional National Research Service Awards. Grants may not be made to individuals as grantees in a foreign country.

4. Transfer of Support or Addition of a Foreign Component. Grants may not be transferred to or between foreign institutions. Transfer from a foreign to a domestic institution may be approved administratively by the IC. The addition of a foreign component requires prior approval for all recipients, regardless of the terms of award.

5. Department of State (DOS) Concurrence. The DOS requires that proposed Research and Development which is to be conducted in a foreign country**,** and proposed acquisition of human materials from sources in a foreign country, must be reviewed by the DOS to assure conformance with the international policies of the U.S. Government**.**

The NIH must obtain concurrence from the DOS before making any new or competing continuation awards to a foreign institution. For projects with a substantial foreign component, awards for the foreign components may not be made until DOS concurrence is obtained. Domestic components, however, may be made whenever the awarding IC deems it appropriate**.**

6. Supplements and Changes in Mechanisms of Support or Principal Investigator. If the parent grant previously received clearance from FIC/DOS, then new administrative or competitive supplements, and changes in mechanisms of support (grant/cooperative agreement/contract), or changes in the principal investigator, do not require additional review. Exceptions are: (1) if the supplement is to work in a new site or new foreign country; (2) if the supplement substantially changes the objectives of the research grant; and, (3) if both a new investigator and a new grantee are proposed.

7. Conferences. Conferences (R13s) supported by grants or cooperative agreements no longer require clearance by the FIC/DOS**.**

8. Responsibility. On behalf of the Director, NIH, the Fogarty International Center serves as the focal point at the NIH for the coordination of all grants to foreign institutions in terms of their relation to intergovernmental arrangements, overall DHHS policy, U.S. foreign policy interests, and NIH interagency agreements. The FIC makes all necessary contacts with the DOS.

9. Beginning with awards issued in FY2002, limited F&A costs (8%, exclusive of equipment for Administrative costs) may be provided on competing grants to foreign institutions and international organizations. This provision is to allow for the support of costs incurred to provide for compliance with DHHS and NIH requirements including but not limited to: the protection of human subjects, the welfare of animals, financial conflict of interest, and invention reporting. No funds are provided for Facility costs.

H. Procedures for Review:

Foreign research grant applications are received by the Center for Scientific Review (CSR), NIH, and assigned to an appropriate initial review group and to an awarding IC and its National Advisory Council or Board.

1. Initial Review. For applications from a foreign institution the summary statement will have a special section (heading in caps) which covers the criteria in Section G.1.a., such as the special resources or characteristics of the research project (e.g., human subjects, animals, disease, equipment, techniques), whether similar research is being done in the United States, and whether there is a need for additional research in this area.

2. Advisory Council or Board. No application from a foreign institution may be awarded without it having been called to the attention of and having received the approval of a National Advisory Council or Board. In approving foreign applications the Council or Board will consider why the application is of special interest to the awarding IC.

3. Program Staff. Program staff must document in the official grant file why each application from a foreign institution has been selected for an award. Information from the summary statement and the discussion of the Council or Board are included as part of the documentation, as well as the staff rationale for selection based on the criteria as specified in G.1.a.-d.

I. IC Procedures:

1. General. Following each Council or Board meeting, the awarding IC determines which foreign research grants it proposes to award. In the interim between Council or Board recommendation and DOS concurrence, any inquiry from the applicant concerning the status of the application will be answered in terms of "not yet approved for funding."

2. Advance Review. Request for DOS concurrence may be made in advance of the Advisory Council or Board consideration if IC staff determines, on the basis of priority score and program relevance, that an application has the potential for funding.

3. Substantial Foreign Component. Proposed new and competing continuation awards to U.S. institutions for projects with a substantial foreign component must be reviewed by FIC to determine if the concurrence of the DOS is necessary prior to award. FIC will obtain DOS concurrence, if necessary.

4. Review by Department of State. No new or competing continuation foreign award may be made without the concurrence of the DOS. The FIC makes all contacts in matters requiring concurrence of the DOS. If an awarding IC expects to make a foreign award, the FIC sends the

necessary documents to the DOS. Concurrence is based upon a determination by the DOS that the proposed award is consonant with U.S. foreign policy objectives.

5. Procedure. See Appendix.

J. Fogarty International Center Procedures for Review and Coordination:

FIC Review. The Fogarty International Center, Division of International Relations (FIC/DIR) reviews the documents for conformance to the criteria cited in G.1.a-d. Additionally, FIC/DIR will review each proposed award to determine adequacy for the DOS review for conformance of the project with U.S. foreign policy. If satisfactory, FIC/DIR will forward the necessary documents to DOS for review and concurrence as appropriate. After review, DOS notifies FIC of either concurrence or non-concurrence of proposed award. FIC keeps a copy of DOS notification and forwards the original to the awarding IC. Should a clearance be disapproved, the clearance documents will be returned to the IC with an explanation of the disapproval. If desired by the IC, FIC/DIR will arrange for appeal of clearance recommendation with DOS. Please note the FIC/DIR and DOS review may take up to six weeks.

K. Exceptions to Allowable Costs and Assurance Requirements:

1. Unallowable Costs. Costs for the following items are not allowable:

a. alterations and renovations;

b. custom and import duties; including consular fees, customs surtax, value-added taxes, and other related charges; and

c. F&A costs. Full F&A will not be allowed with the exception of the American University of Beirut and the World Health Organization. However, limited F&A (8%, minus equipment for Administrative costs) will be provided to support compliance costs (e.g., human subjects, welfare of animals, financial conflict of interest, invention reporting, etc.). No Facility costs will be provided.

2. Civil Rights, Disabled, Sex and Age Discrimination Assurances are not required for grants to foreign institutions and international organizations. Assurances for Research Misconduct, Lobbying, Drug-Free Workplace, Delinquent Federal Debt, Financial Conflict of Interest and Debarment are required.

L. Payment Responsibilities and Procedures:

The Office of Financial Management, Government Accounting Section, has the responsibility for the payment (U.S. dollars only) for grants awarded to foreign grant recipients. Any questions

regarding payments issued to foreign grantees may be addressed to the office below:

National Institutes of Health
Office of Financial Management
Financial Services Branch
Government Accounting Section
Building 31, Room B1B05, MSC 2050
9000 Rockville Pike
Bethesda, Maryland 20892-2050
Telephone: 301-402-9123
Fax: 301-402-4934

If the amount of the award is $15,000 or less, one advance payment in lump-sum is processed. If the amount of the award is greater than $15,000, an advance payment equal to one-fourth of the amount is processed at the beginning of the budget period with succeeding quarterly payments processed in advance.

If the amount of funds advanced to the institution on a quarterly basis is insufficient to meet the cash requirements of the grant, the institution must make a written request to the awarding IC for any additional funds needed in excess of those provided on a quarterly basis.

M. Records Retention and Disposal:

All records (**e-mail** and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743, "Keeping and Destroying Records, Appendix 1, NIH Records Control Schedule," Item 4000 which covers NIH Grants and Awards and item 1100-G which covers Advisory Councils and Committee Management. Refer to the NIH Chapter for specific disposition instructions.

NIH e-mail messages: NIH e-mail messages (messages including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. **These records must be maintained in accordance with current NIH Records Management guidelines. If necessary, back-up file capability should be created for this purpose. Contact your I/C Records Officer for additional information.**

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of

time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

N. Accountability and Management Controls Citation:

The purpose of this manual issuance is to state policies and procedures for grants to foreign organizations or to domestic organizations with substantial foreign components.

1. The Office Responsible for Reviewing Management Controls Relative to this Chapter: The Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research (OER), is accountable for the method used to ensure that management controls in grants administration are implemented.

2. Frequency of Review: Ongoing reviews will occur as scheduled or on an ad hoc basis.

3. Method of Review: Responsibility for accountability and management controls for this chapter reside with the OPERA, OER. The frequency of review will be no less often than every four years. The Method of Review will be Other Review.

OPERA will use the NIH internal grants management compliance model (GMCM) to assess compliance with the policies stated in this issuance. The GMCM contains a file review component to ensure that I/C grant files are properly maintained and processed with regard to policies associated with foreign and international grantees. Reports of findings and recommendations resulting from GMCM reviews or other similar types of reviews will be provided to the Grants Management Compliance Board for appropriate action. Common issues will be brought to the Grants Management Advisory Committee for resolution and corrective action. Depending upon the nature and the extent of problems found, if any, the Director, OPERA, may recommend additional policy guidance or training for grants management staff.

4. Review Reports are Sent to: The DDER and the Director, OPERA, OER.

Appendix

INTRODUCTION

The following information and procedures provide detailed instructions in the management of foreign research grants; policy matters are contained in the body of the manual chapter.

BACKGROUND

The Department of State (DOS) has the authority under the Foreign Relations Authorization Act, to examine all international U.S. Government activities for its impact on national security and foreign policy. To oversee activities related to NIH awards, FIC has established a formal notification and concurrence process whereby the FIC collects and forwards information to the Department of State regarding proposed grants to foreign institutions, and transmits cables through Department of State to U.S. Embassies. Please note that grant content considered as sensitive include the following: vaccine-related research, HIV/AIDS research, drug abuse, involvement of pregnant women, children and primates in research, and politically sensitive regions.

The foreign clearance process can be started at various times - post-IRG, pre-Council, post-Council - and each IC varies in when it is started. Most ICs initiate the clearance process in the grants management office. Regardless of when or where the process begins, ICs must be reasonably certain that a positive funding decision will be made at the time the clearance documents are forwarded to FIC.

WHAT CONSTITUTES FOREIGN INVOLVEMENT?

Any activity as described below including involvement of human and animal subjects (see "Completing Research Objectives" below) whether or not grant funds are expended.

Any significant element or segment of the project which is to be performed outside the U. S., either by the grantee or by a researcher employed by a foreign institution.

Any extensive foreign travel by grantee project staff for the purpose of data collection, surveying, sample collection, etc. Foreign travel for consultation is not considered a substantial foreign component.

FIC will determine if foreign clearance is necessary on a case-by-case basis. All grants with foreign involvement should be evaluated for determination of State Department clearance.

CLEARANCE PROCESS

Include one copy of the following:

NIH Form 1820 (Rev.1/96) (a form for each foreign component)
Copy of summary statement
Copy of grant application
Related correspondence

On the clearance package, attach a memo or route slip with the following information: the name of the IC staff contact submitting the package with phone and fax numbers; address of where to

return signed 1820 form; state if the foreign involvement is a new foreign activity. If the grant is a renewal of a previous foreign clearance attach a copy of the previously cleared NIH form 1820.

NIH FORM **1820** - NOTIFICATION OF PROPOSAL TO MAKE AN AWARD

If multiple foreign countries are involved, complete an NIH form 1820 for each country.

Indicate domestic PI's name and complete organizational address in area, "Domestic PI."

Indicate foreign collaborating investigator's name and complete organizational address in area, "Foreign PI." When there is no foreign principal or collaborating investigator, document the name and address of the domestic PI's local contact in the foreign country.

Date of birth, place of birth and residency are no longer necessary.

It is important that the area documenting estimated total dollar award be complete, with the top line reflecting the total annual domestic funding and the lower line reflecting the total annual foreign funding

COMPLETING RESEARCH OBJECTIVES:

Research objectives need to be written in technical terms to the greatest extent possible.

Supply a brief description of overall grant objectives and research activity in the foreign country.

State where the research is being conducted, i.e., hospital, laboratory, outpatient clinic, and indicate the city or town where research will take place. In the case of "field work" describe where the work will be done.

On whom are the investigators conducting research? e.g., women, children, diabetics, control subjects, primates, rats, rabbits, etc.

Documentation of human subject involvement: Describe the number of study and control subjects enrolled in the project, the ratio of gender and ethnic origin. Include a description of the research being conducted on study subjects. For example, are the study and control subjects providing blood or urine samples, tissue specimens or are they involved in drug/placebo clinical trials? Indicate the duration of human subject involvement.

For the exportation of animals or plants from the foreign site, state if government permits have been obtained?

Investigators working abroad are encouraged to apply high standards of treatment and care in research involving animals, similar to the principles outlined in the PHS Animal Welfare Policy.

The Office of Laboratory Animal Welfare (OLAW) must have a "Statement of Compliance with Standards for Humane Care and Use of Laboratory Animals by Foreign Institutions" on file for all foreign institutions with activities involving animals.

If additional space is needed for research objectives, please attach an addendum.

FOR ACTIVITY INVOLVING HUMAN SUBJECTS AND/OR ANIMAL SUBJECTS

Check appropriate box to indicate status of negotiation of human or animal subject assurances with Office of Human Research Protection (OHRP) and OLAW, respectively, and give assurance identification numbers if applicable.

NOTE: The grantee should not be referred to FIC for the status of the clearance process. The grants specialist serves as liaison between the grantee and FIC. Attempts by the principal investigator to contact either the FIC or the DOS only creates delays in the clearance process. The grants specialist may instead inquire on behalf of the PI with the FIC.

TERMS AND CONDITIONS APPLICABLE TO FOREIGN GRANTS

In general, the policies and requirements applicable to domestic research grants are applicable to grants made to foreign institutions and international organizations. There are, however, certain exceptions and special conditions listed below:

Single-case Deviations. The awarding IC may make single-case deviations in instances involving NIH policy, e.g., to award an excepted grant mechanism (G.3.), to transfer to or between foreign institutions (G.4.) and to award patient care costs. In the case of transferring to or between foreign institutions, the awarding IC must ensure that the special criteria for making a foreign award are met. This authority for a single-case deviation includes transferring a domestic grant to a foreign entity, as this requires prior approval.

Currency Exchange. All requests for funds, including the budget contained in the application, shall be stated in U.S. dollars. Once an award is made, the NIH will not compensate foreign grantees for currency exchange fluctuations through the issuance of supplemental awards. Foreign grantee institutions are strongly urged to use U. S. banks to ensure that payments will arrive on time.

Unallowable Costs. Costs for the following items are not allowable:

1. Alterations and renovations;

2. Custom and import duties; including consular fees, customs surtax, value-added taxes and other related charges; and

3. F&A. Beginning with awards issued in FY2002, limited F&A (8% minus equipment for Administrative costs) may be provided on competing awards as detailed in Section K. No Facility costs will be provided.

Patient Care Costs. Patient care costs are provided only in exceptional circumstances.

Equipment. Management and accountability requirements for equipment purchased with NIH grant funds are identical to those for domestic institutions as specified in CFR Title 45 Part 74.

Reports and Records. Foreign grantee institutions must submit reports in English and in terms of U.S. dollars. Record retention and audit requirements are the same as those for grants to domestic institutions.

Expanded Authorities. Foreign grantee institutions are included in Expanded Authorities. Inclusion in the Streamlined Non-competing award process (SNAP) process is at the discretion of the awarding IC.

Assurances. Assurances for Civil Rights, Disabled, Sex and Age Discrimination are not required for grants to foreign institutions. Assurances for Research Misconduct, Lobbying, Drug-Free Workplace, Delinquent Federal Debt, Financial Conflict of Interest and Debarment (with the exception of foreign governments and international organizations) are required.

Audit. Foreign grantees are subject to the audit requirements as set forth in OMB Circular A-133. A-133 requires that any recipient or sub-recipient that expends $300,000 or more in a year in Federal awards shall have a single or program-specific audit conducted for that year.

Debarment/Suspension. If the awarding IC anticipates the pursuit of debarment or suspension then contact with the FIC is crucial prior to initiating any other action.

Annual Reporting Requirements. FIC compiles a list annually of awards made to domestic organizations with foreign components. To ensure accuracy, FIC forwards the list of awards made during the previous fiscal year to IC Executive Officers and Grants Management Officers for their review and verification of accuracy. ICs are requested to verify the accuracy of these numbers in writing or, alternatively, ICs may provide a statement to the FIC Executive Officer that the Notification of Proposal to Make an Award (NIH Form 1820) is to be used by FIC to verify the data.

CLEARANCE PACKAGE SUBMISSION:

Forward the complete package of material to:

Division of International Relations, FIC
Building 31, Room B2C11, MSC 2220

Phone: 301-496-4784
Fax: 301-480-3414

Department of Health and Human Services - National Institutes of Health

DATE

_____

NEW FOREIGN CLEARANCE

or

RENEWAL OF FORE CLEARANCE

NOTIFICATION OF PROPOSAL

TO MAKE AN AWARD

TO U.S. Department of State, Bureau of Oceans and International Environmental and Scientific Affai

THROUGH NIH, Fogarty International Center, Division of International Relations

FROM

NAME, TITLE, IC

The National Institutes of Health is considering an award to the following grantee/contractor for the amount and period indicated below. The project is considered important and relevant to the program objectives of the National Institutes of Health. A copy of the application or proposal describing the research or training project involved is attached. It is requested that the Department of Sta review this application or proposal from the standp United States foreign policy objectives, keeping in that the purpose of the proposed award is primarily advance the medical sciences in the United States a health of the people of the United States.

Title of Project:

Grant or Contract No:

ESTIMATED TOTAL DOLLAR AWARD (DOMESTIC A FOREIGN)

DOMESTIC PRINCIPAL INVESTIGATOR'S NAME, ORGANIZATION AND ADDRESS

1st Year 2nd Year 3rd Year 4th Year 5th Year

ESTIMATED FOREIGN COMPONENT DOLLAR AWAR

1st Year 2nd Year 3rd Year 4th Year 5th Year

***FOREIGN** PRINCIPAL OR COLLABORATING INVESTIGATOR(S) NAME, ORGANIZATION, CITY COUNTRY

***IF MULTIPLE INVESTIGATORS OR COUNTRIES ARE INVOLVED, COMPLETE A COPY OF NIH 1820 FOR EACH FOREIGN COUNTRY INVOLVED IN PROJECT**

RESEARCH OBJECTIVES (If more space is needed attach an addendum)

HUMAN SUBJECT INVOLVEMENT

None Pending Assurance No.

ANIMAL SUBJECT INVOLVEMENT

None Pending Assurance No.

SIGNATURE OF IC AWARDING/CONTRACTING OFFICIAL

SIGNATURE OF FIC PROGRAM OFFICER

SIGNATURE OF STATE DEPARTMENT OFFICIAL

FNo objection to award
C
RAward not recommended

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